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09/982,688	10/18/2001	Marc Dubois	8571:46	8632

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Robert Bertani, LLP  
P.O. Box 26780  
Austin, TX 78755

EXAMINER

PALADINI, ALBERT WILLIAM

ART UNIT PAPER NUMBER

2125

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/982,688

Applicant(s)

DUBOIS ET AL.

Examiner

Albert W Paladini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/23/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Relating to figure 1, lines 7-9 on page 10 state "For example, the model processor 16 may derive an optimized operating characteristic of the sonic signal generator 12." Referring to figure 2, lines 20-21 on page 15 state "The sonic energy signal generator 52 has an operating characteristic."

Under the chapter entitled Optimization in the book System Engineering Tools, the author states on page 437, "optimum, as an adjective again is defined as the 'best' and also as 'most favorable or most conducive to a given end especially under fixed conditions.'" The specification uses the term optimized throughout, but does provide any specific "end" or objective to be achieved. For example, the required input energy might be minimized, the cost of the sonic energy signal generator may be minimized, the number of components might be minimized, etc.

The reference throughout the specification to "operating characteristic" is not clear. In order to understand the proposed invention, it is necessary to clearly explain

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operating characteristic and optimization, and their relation to each other. Hudziak (4440173) states from line 56 in column 1 to line 31 in column 2 "The present invention is directed to a body stimulation system of the type having an external unit for generating and transmitting radio frequency programming signals and an implantable unit including a stimulation signal generator with at least one alterable operating characteristic, an output system for delivering a stimulation signal to the desired body site and circuitry responsive to received programming signals for establishing the operating characteristic in predetermined correspondence therewith. The output delivering system is connected to the operating characteristic establishing circuitry and receives the programming signals and delivers the same to the operating characteristic establishing circuitry. In a preferred embodiment, the output delivering system includes a stimulation delivering lead, the lead receiving and delivering the programming signals to the operating characteristic establishing circuitry. Thus, antenna coils of prior art programmable devices are eliminated, without elimination of their function. In addition, in the event that the stimulation signal generator is hermetically sealed in a housing, as described above, that housing does not interfere with the reception of the programming signals by the implantable device. To assure the integrity of the programming signal, the external device is prevented from transmitting a programming signal during a stimulation signal. Preferably, such transmission is prevented for a predetermined time following a stimulation signal. The predetermined period may be such that the external device is activated to transmit a programming signal only during the refractory period of the tissue being stimulated. In order to limit programming of the implantable device by extraneous signals, the operating characteristic establishing circuitry may be rendered responsive to receive programming signals only during the occurrence of second externally generated signals having characteristics discriminable from the characteristics of the programming signals. In a preferred embodiment, the programming signals comprise radio frequency signals and the second signals comprise magnetic signals. In the event that the stimulation signal generator is a pulse generator, it may be caused to operate at a fixed rate during the occurrence of the second externally generated signals." The specification and the claims refer to a single operating characteristic, but as demonstrated by Hudziak (4440173), a signal generator may have more than one operating characteristic. To understand the invention, it is necessary to explain the specific operating characteristic referred to and the conditions for optimization.

Appropriate correction and clarification is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject-matter, which the applicant regards as his invention.

4. Claims 1-53, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

### Claim 1

Line 3 recites "a sonic energy signal generator operating with an operating characteristic." A signal generator may have more than one operating characteristic as demonstrated by Hudziak (4440173, who states from line 56 in column 1 to line 31 in column 2 "The present invention is directed to a body stimulation system of the type having an external unit for generating and transmitting radio frequency programming signals and an implantable unit including a stimulation signal generator with at least one alterable operating characteristic, an output system for delivering a stimulation signal to the desired body site and circuitry responsive to received programming signals for establishing the operating characteristic in predetermined correspondence therewith. The output delivering system is connected to the operating characteristic establishing circuitry and receives the programming signals and delivers the same to the operating characteristic establishing circuitry. In a preferred embodiment, the output delivering system includes a stimulation delivering lead, the lead receiving and delivering the programming signals to the operating characteristic establishing circuitry. Thus, antenna coils of prior art programmable devices are eliminated, without elimination of their function. In addition, in the event that the stimulation signal generator is hermetically sealed in a housing, as described above, that housing does not interfere with the reception of the programming signals by the implantable device. To assure the integrity of the programming signal, the external device is prevented from transmitting a programming signal during a stimulation signal. Preferably, such transmission is prevented for a predetermined time following a stimulation signal. The predetermined period may be such that the external device is activated to transmit a

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programming signal only during the refractory period of the tissue being stimulated. In order to limit programming of the implantable device by extraneous signals, the operating characteristic establishing circuitry may be rendered responsive to receive programming signals only during the occurrence of second externally generated signals having characteristics discriminable from the characteristics of the programming signals. In a preferred embodiment, the programming signals comprise radio frequency signals and the second signals comprise magnetic signals. In the event that the stimulation signal generator is a pulse generator, it may be caused to operate at a fixed rate during the occurrence of the second externally generated signals."

Lines 6-7 recite "the sonic energy signal generator initiating the particular sonic energy signal using the operating characteristic." Since there are more than one possible operating characteristics, as demonstrated above, it is necessary to explain which operating characteristic initiates the particular energy signal.

### Claim 15

Lines 4-5 recite "the sonic energy signal having properties determined by an operating state of the system. Hudziak (4440173) states from line 56 in column 1 to line 31 in column 2 "The present invention is directed to a body stimulation system of the type having an external unit for generating and transmitting radio frequency programming signals and an implantable unit including a stimulation signal generator with at least one alterable operating characteristic, an output system for delivering a stimulation signal to the desired body site and circuitry responsive to received programming signals for establishing the operating characteristic in predetermined correspondence therewith. The output delivering system is connected to the operating characteristic establishing circuitry and receives the programming signals and delivers the same to the operating characteristic establishing circuitry. In a preferred embodiment, the output delivering system includes a stimulation delivering lead, the lead receiving and delivering the programming signals to the operating characteristic establishing circuitry. Thus, antenna coils of prior art programmable devices are eliminated, without elimination of their function. In

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addition, in the event that the stimulation signal generator is hermetically sealed in a housing, as described above, that housing does not interfere with the reception of the programming signals by the implantable device. To assure the integrity of the programming signal, the external device is prevented from transmitting a programming signal during a stimulation signal. Preferably, such transmission is prevented for a predetermined time following a stimulation signal. The predetermined period may be such that the external device is activated to transmit a programming signal only during the refractory period of the tissue being stimulated. In order to limit programming of the implantable device by extraneous signals, the operating characteristic establishing circuitry may be rendered responsive to receive programming signals only during the occurrence of second externally generated signals having characteristics discriminable from the characteristics of the programming signals. In a preferred embodiment, the programming signals comprise radio frequency signals and the second signals comprise magnetic signals. In the event that the stimulation signal generator is a pulse generator, it may be caused to operate at a fixed rate during the occurrence of the second externally generated signals." As demonstrated by Hudziak, a signal generator may have more than one operating state. To understand the invention, it is necessary to explain the specific operating characteristic recited.

Lines 7-8 recite, "a signal analyzer communicatively coupled to the sonic energy detector, that determines if a sonic energy signal is an optimal signal." The term "optimum" in this context must be explained. Under the chapter entitled Optimization in the book "System Engineering Tools, the author states on page 8, optimum, as an adjective again is defined as the 'best' and also as 'most favorable or most conducive to a given end especially under fixed conditions.'" The conditions, which define an optimal signal, are not explained. The claim does also not explain what the "signal analyzer" measures.

### Claim 27

Line 3 recites, "deriving an optimized operating characteristic of a sonic energy signal generator." A signal generator can have more than one operating characteristic and the conditions for optimization are not recited.

Under the chapter entitled Optimization in the book "System Engineering Tools, the author states on page 8, optimum, as an adjective again is defined as the 'best' and also as 'most favorable or most conducive to a given end especially under fixed conditions.'" The recitation uses the term optimized, but does provide any specific "end" or objective to be achieved. For example, the required input energy might be minimized,

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the cost of the sonic energy signal generator may be minimized, the number of components might be minimized, etc.

Hudziak (4440173) states from line 56 in column 1 to line 31 in column 2 "The present invention is directed to a body stimulation system of the type having an external unit for generating and transmitting radio frequency programming signals and an implantable unit including a stimulation signal generator with at least one alterable operating characteristic, an output system for delivering a stimulation signal to the desired body site and circuitry responsive to received programming signals for establishing the operating characteristic in predetermined correspondence therewith. The output delivering system is connected to the operating characteristic establishing circuitry and receives the programming signals and delivers the same to the operating characteristic establishing circuitry. In a preferred embodiment, the output delivering system includes a stimulation delivering lead, the lead receiving and delivering the programming signals to the operating characteristic establishing circuitry. Thus, antenna coils of prior art programmable devices are eliminated, without elimination of their function. In addition, in the event that the stimulation signal generator is hermetically sealed in a housing, as described above, that housing does not interfere with the reception of the programming signals by the implantable device. To assure the integrity of the programming signal, the external device is prevented from transmitting a programming signal during a stimulation signal. Preferably, such transmission is prevented for a predetermined time following a stimulation signal. The predetermined period may be such that the external device is activated to transmit a programming signal only during the refractory period of the tissue being stimulated. In order to limit programming of the implantable device by extraneous signals, the operating characteristic establishing circuitry may be rendered responsive to receive programming signals only during the occurrence of second externally generated signals having characteristics discriminable from the characteristics of the programming signals. In a preferred embodiment, the programming signals comprise radio frequency signals and the second signals comprise magnetic signals. In the event that the stimulation signal generator is a pulse generator, it may be caused to operate at a fixed rate during the occurrence of the second externally generated signals." The specification and the claims refer to a single operating characteristic, but as demonstrated by Hudziak (4440173), a signal generator may have more than one operating characteristic. To understand the invention, it is necessary to explain the specific operating characteristic referred to and the conditions for optimization.

### Claim 28

Line 1 recites "A method for generating an improved sonic energy signal", but does not define what is meant by improved.

Lines 9-10 recite, "selectively adjusting the sonic energy signal generator to operate in the second state to produce a second sonic energy signal." The adverb "selectively" appears to be unnecessary. There is no reason to believe that the sonic



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energy signal is improved in this second state, since the criterion for improvement has not been defined.

#### **Claim 40**

Line 9 recites, "determining if the first sonic energy signal requires improvement." There is no criteria recited which defines improvement, so that it is not understood how the determination is made.

Lines 10-11 recite "selectively, based on the output of the step determining" deriving the second state of operation of the sonic generating device." Assuming that the second state is intended to be an improved state, it is not understood how it can be determined since the criteria for improvement is not defined.

Lines 12-13 recite "producing a second sonic energy signal with the sonic energy generating device operating in the second state of operation." The criteria for improvement must be known, and the parameters, which need to be adjusted to achieve this improvement, must be known in order to achieve this step.

#### **Claim 55**

Lines 8-9 recite "the model processor determining a new operating characteristic of the sonic energy signal generator from the measured signal." There is no recitation of which variables are used and how the model processor uses the measured signal to determine a new operating characteristic. There is no recitation, which explains how determining this new operating characteristic generates the improved sonic energy signal as required by the preamble. There are no criteria for improvement recited.

Appropriate correction and clarification are required.

5. Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

#### **Claim 54**

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Lines 5-6 recite, "determining the initial operating state of a sonic energy signal generator, a model processor determining the initial operating state." There are no steps preceding this step, which provides input to the processor to determine an initial operating state. Without specific steps and included criteria, the processor has no criteria to make this determination.

Lines 10-11 recite, "determining if another operating state of the sonic energy signal generator is justified." The term "justified" is vague. There is no clear physical measurement, which can determination justification.

### **Claim 55**

Lines 5-6 recite, "determining if the first sonic energy signal, produced with the signal energy signal generator can be improved." There is no definition of improvement provided in the preceding steps.

Appropriate correction and clarification is required.

6. Terminology such as operating characteristics is used throughout the specification and the claims to imply operational attributes to a system or process. But these terms are not sufficiently defined to describe the measurable variables of a functionally operating system.

Terminology such as optimize, improvement, and justify are used throughout the specification and claim to imply a process of improving, but no specific measurements, criteria, and methodology for improvement are provided.

Each specific rejection must be addressed.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (4276779).

This rejection is made to the extent that the claims are understood.

Davis discloses an array of sonic transducers, and in figure 1 signal generator provides the waveform of the signal to be transmitted. Knob 62 of switch 60 controls an operating characteristic of the signal generator to select the optimum mode of transmission in accordance with the range of distances to the subject matter being imaged. Selection of the optimum mode implies that there is no room for improvement for the specific conditions and constraints of the system.

#### ***Relevant Prior Art***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Auer (3675190) discloses a sonic presence detector system with one embodiment where the transmitter output terminals are disconnected from the receiver amplifier during the transmitting periods while these same output terminals connect to the receiver amplifier during the receiving interval. This results in improved performance in two ways. First, the transmitter output signal is increased by the reduction of the receiver amplifier loading, and second, the large attenuation of the received signal by the load resistors is for all practical purposes eliminated.

Suter (3715672) discloses a sonic detection apparatus where one of the objects of the invention is to improve the operating characteristics of the prior Doppler swimmer detector by providing automatic adjustment of the band pass filters to compensate for variations in the Doppler frequency spectra caused by changes in the river velocity. Another object of the invention is to prevent accidental triggering of the alarm by gradual changes in the ambient level. A further object is to make the rate and direction of change in the gain of each amplified band pass filter dependent only on whether a registered level is above or below threshold so that a steady rate of gain adjustment, non-proportional to the amplitude, is obtained. Still another object is to improve the display system for the outputs of the band pass filters.

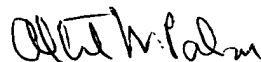
Kenney (5161128) discloses a capacitive transducer system used to control the operating characteristics of a microprocessor-based controller to correct for an imbalance. Kenny teaches the used of capacitive transducers in generators and receivers of sonic signals including audible and ultrasonic signals.

10. Any inquiry concerning this communication or earlier communication from the examiner should be direct to Albert W. Paladini whose telephone number is (572) 272-3748. The examiner can normally be reached from 7:30 to 3:30 PM on Monday, Tuesday, Thursday, and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Leo P. Picard, can be reached on (572) 272-3749. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

January 6, 2005

  
Albert W. Paladini  
Primary Examiner  
Art Unit 2125